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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/210,747 12/15/98 BRIGGS

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EXAMINER

PORTNER, V

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

12/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/210,747

Applicant(s)

Briggs et al

Examiner

Portner

Group Art Unit

1641



☒ Responsive to communication(s) filed on 7/15/99 and 9/16/99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 34, 35, and 38-50 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 34, 35, and 38-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 34-35, and 38-50 are pending; all claims have been amended.

Rejections Maintained

1. Claims 34-35 and 38-44 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,849,305 for reasons of record, as well as claim 5 of US Pat. 5,824,525 and claims 13-16 of US Pat. 5,587,305.
2. Claims 34-35, 38,39,41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Homchampa et al (1992, reference submitted by Applicant for reasons of record as applied to claims 34-37(23-26).
3. Claims 34-35 and 38-50 remain rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to site directed mutations of *Pasteurella haemolytica* using aroA and PhaI, as well as leukotoxin operon (C,A,B,D) and neuraminidase genes, and specific

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compositions for the treatment of cattle and sheep for reasons of record.

New Claims and Claim Limitations/ New Grounds of rejection

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claim 40 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim of prior claim 12 of US Pat. 5,587,305. This is a double patenting rejection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 38-39, 43,44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claims 38-39 and 43-44 recite modes of administration of the composition but these limitations are not further limiting of the claim from which they depend because a mode of administration does not further define the components present in the composition being claimed and the recitation of an intended use does not define a vaccine component.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
10. Claims 34, 38,39, 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Gentry et al (1988).

Gentry et al disclose strains of *Pasteurella haemolytica* which produced various degrees of toxicity when

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administered as a composition to cattle. The variation evidenced by each of the five strains is indicative of differences in the genetic make up of each of the leukotoxins and therefore represent naturally occurring mutations present in *Pasteurella haemolytica* strains. Therefore, this reference anticipates the now claimed invention.

11. Claims 34, 38, 39, 47 rejected under 35 U.S.C. 102(b) as being anticipated by Cruz et al (1990).

Cruz et al disclose strains of *Pasteurella haemolytica* which were modified through a series of internal deletion in the lktA (leukotoxin-A) gene. Inherently these strains would have the now claimed characteristics and therefore anticipates the now claimed invention.

Response to Arguments

12. Applicant has amended the claims to recite a Markush Group of mutations and states that this has been done "[I]n order to advance prosecution claim 34 has been amended to recite that the mutation occurs in a gene selected from the group consisting of aroA, PhaI, leukotoxin C, leukotoxin A, leukotoxin-B, leukotoxin-D, and neuraminidase genes." and

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asserts that the "DNA which is introduced both contains the mutation and is methylated by an enzyme having the same sequence specificity as PhaI"

13. Applicant's arguments filed with respect the newly submitted claim limitations and the rejection under 35 USC 112, first paragraph (scope) have been fully considered but they are not persuasive because the instant specification only provides original descriptive support for compositions which comprises PhaI and AroA mutations which in turn may be in association with other genetic mutations in the leukotoxin C, leukotoxin A, leukotoxin B, leukotoxin D, and neuramidinidase genes. The claims are NOT limited to the introduction of DNA into the genes which encode the recited proteins but any type of mutation is recited. There in NO requirement that the mutation by through methylation. Therefore, the arguments made of record are not commensurate in scope with the instantly claimed invention.

14. **Conclusion**

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly,

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THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group ~~1641~~.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

vgp

December 3, 1999


JAMES C. HOUSEL 12/4/99
SUPERVISORY PATENT EXAMINER